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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,486	10/04/2000	Geoffrey Thomas Andrews	1652-11	8045

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NIXON & VANDERHYE P.C.  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714

EXAMINER

THOMPSON, MICHAEL M

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

<b>Office Action Summary</b>	Application No. 09/678,486	Applicant(s) ANDREWS ET AL.	
	Examiner Michael M. Thompson	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2002.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/241,293.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group 1, claims 1-11 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group 2, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

### *Priority*

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/241,293, filed on 01 February, 1999.

### *Information Disclosure Statement*

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or a submitted PTO-1449, they have not been considered.

***Claim Objections***

5. Claim 11 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It appears that claim 11 is almost identical to claim 1 in that the scope of the claim appears to be identical to the scope and limitations of the parent claim.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites the limitation "the intermediate portion" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 1 recites the limitation "the intermediate" in line 15. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 7 recites the limitation "the critical angle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 8 recites the limitation "the wider diameter portion" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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12. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by LeVeen et al. (4,448,195). LeVeen et al. teaches a hollow radially expandable balloon member having terminal portions with a diameter smaller than an intermediate portion, a fluid impervious wall of polyurethane wherein the wall has reinforcing fibers integrally with the wall material, a catheter having a tube portion whereby the balloon member can be inflated and deflated by the catheter or tube portion. Please note that it is the Examiner's position that the reinforcing fibers inherently limit radial expansion of the balloon device.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al. in view of Guzauskas (5,747,553). LeVeen et al. further teaches that the fibrous reinforcement can be made of woven glass or *fine fibers of other materials*. LeVeen et al. teaches all of the limitations of the claims except for explicitly stating that the fibrous reinforcement can be made of a braid of filaments of a polymer in the form of two opposed helices and are orientated to one another at or adjacent to the critical angle of the braid or made of a polyester polymer or made of a shape memory polymer. Guzauskas teaches polymeric compositions with fibrous fillers such as polyester that are in a braided configuration. He further teaches that a suitable composition for the reinforcing fibers would be Mylar, a well known material having shape memory properties. It would have been obvious to one of ordinary skill in the art at the time of invention to have modified the fibrous reinforcement layer of LeVeen et al. with the fibrous polymer reinforcement of polyester in a braided fashion or a shape memory material of Mylar as taught by Guzauskas for the well known purpose of enhancing the strength and stiffness of the inflated balloon of LeVeen et al. Please note that it is also the Examiner's position that the further limitations with respect to the helices and critical angle of the braided structure as taught by Applicant are inherent in all braided structures. Furthermore, when considering the instant

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rejection it is further the Examiner's position that a braided structure is clearly an obvious equivalent of a woven structure in the art of reinforcing structures.

18. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al. in view of Breslow (3,616,199). LeVeen et al. teaches all of the limitations of the claims except for the reinforcing fibers being made of a polyester polymer. Breslow teaches a fibrous polyester reinforcing material to a rubber stock such as polyurethane. It would have been obvious to one of ordinary skill in the art, at the time of invention to have simply substituted or modified the reinforcing fibers taught by LeVeen et al. with the reinforcing fibers and materials taught by Breslow for the well known purpose of enhancing the strength and stiffness of the inflated balloon taught by LeVeen et al

19. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al.. LeVeen et al., at least, inherently teaches limiting radial expansion of the intermediate portion. LeVeen et al. does not expressly disclose that the limit of radial expansion is not more than 115% of the maximum unstretched radially expanded state. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have provided that the maximum limit of radial expansion to not more than 115% of the maximum unstretched radially expanded state because Applicant has not disclosed that limiting radial expansion to not more than 115% provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with limiting radial expansion to not

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more than any reasonable percent or not more than specifically 115%. Therefore, it would have been an obvious matter of design choice to modify LeVeen et al. to obtain the invention as specified by Applicant for the well known purpose of preventing over-expansion of a balloon device within the vasculature of a patient to prevent rupture or tearing of the vessel.

### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

Patent Examiner

MT 

September 28, 2002

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700